MAR 07 2014

510(k) Summary

Date Prepared: January 24, 2014

Company: Choice Spine, LP
400 Erin Drive, Knoxville, TN 37919
Tel: 865.246.3333 | Fax: 865.246.3334

Regulatory Contact: Kim Finch, Manager of Regulatory Affairs
kfinch@choicespine.net

Trade Name: BLACKBIRD™ Spinal System

Product Class: Class II

Classification: 888.3050 Spinal Interlaminal Fixation Orthosis

Product Codes: KWP

Panel Code: 87

Device Description:

The Choice Spine BLACKBIRD™ Spinal System is a comprehensive system for posterior fixation of the cervical and upper thoracic spine. It is to be implanted posteriorly. The system is composed of polyaxial screws and smooth shaft polyaxial screws in various sizes, set screws, straight rods, pre bent rods, transition rods, rod to rod cross connectors, lateral offset connectors, rod transition connectors, and hooks. All implant components will be made from Ti 6Al 4V-ELI alloy or Cobalt 28- Chromium 6- Molybdenum per ASTM F1537.

Indications for Use:
The BLACKBIRD™ Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion for stabilization of the cervical spine & thoracic spine (C1-T3) for the following conditions:

- degenerative disc disease (DDD; defined as neck pain of discogenic origin with degeneration of the disk as confirmed by history & radiographic studies)
- spondylolisthesis
- trauma
- fracture / dislocation
- spinal stenosis
- atlanto/axial fracture with instability
- tumor
- revision of previous cervical spine surgery

The use of polyaxial screws is limited to placement in the thoracic spine (T1-T3) "for anchoring the construct only" and is not intended to be placed in the cervical spine. The use of the rods and hook components are intended for use in (C1-T3). This system can be linked to a Ø6.0mm rod system such as the Choice Spine Starfire™ Pedicle Screw System.

Predicate Device(s):
The BLACKBIRD™ Spinal System is substantially equivalent to the previously cleared Aesculap (K050979) S4 Spinal System, Theken Spine (K070638) Atoll Cervical-Thoracic System, and Alphatec Spine (K052201, K071380) Solanas Spinal Systems.

Performance Standards:
Performance testing was completed by an independent laboratory following ASTM F1717. The tests included static compression bending, static torsion and dynamic compression bending. Additionally Torsional gripping capacity, axial gripping capacity, flexion extension / cantilever bending results were tested per ASTM 1798-97(20008). The performance testing required is the equivalent same for the predicate devices.

Substantial Equivalence:
The characteristics of the BLACKBIRD™ Spinal System are similar to the predicate devices Aesculap (K050979) S4 Spinal System, Theken Spine (K070638) Atoll Cervical-Thoracic System, and Alphatec Spine (K052201, K071380) Solanas Spinal Systems. Equivalence is based on the similarities of the intended use, design, physical characteristics when compared to the predicates, and system component materials.
Choice Spine concludes that the BLACKBIRD™ Spinal System is substantially equivalent when compared to the predicate legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 7, 2014

Choice Spine, LP
Ms. Kim Finch
Manager of Regulatory Affairs
400 Erin Drive
Knoxville, Tennessee 37919

Re: K133214
Trade/Device Name: Blackbird Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: January 23, 2014
Received: January 28, 2014

Dear Ms. Finch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7.0 Indications for Use

510(k) Number K133214

Device Name: BLACKBIRD™ Spinal System

The BLACKBIRD™ Spinal System is intended to be used in skeletally mature patients as an adjunct to fusion for stabilization of the cervical spine & thoracic spine (C1-T3) for the following conditions:

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133214